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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,212	10/30/2003	David R. Hennings	NSL-501	2780
34313	7590	09/22/2005	EXAMINER	
ORRICK, HERRINGTON & SUTCLIFFE, LLP IP PROSECUTION DEPARTMENT 4 PARK PLAZA SUITE 1600 IRVINE, CA 92614-2558			SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3739	
DATE MAILED: 09/22/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,212	HENNINGS	
	Examiner	Art Unit	
	david shay	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on July 8, 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17, 19-23 and 25-34 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17, 19-23 and 25-34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>February 28, 2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2005 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant argues that Goldman et al. ('084) does not disclose applicants claimed wavelength and continues arguing that the combination of Dew et al. and Goldman et al. is improper because Goldman merely "makes passing reference to the use of lasers." These arguments are not convincing. A careful reading of Goldman et al. ('084) will reveal that at lines 53 through 59, of column 7 Goldman et al. ('084) states "furthermore, although the invention will be described as using RF energy from the electrode, it is to be understood that other forms of energy, such as microwaves, ultrasound direct current circulating heated fluid, radiant light and lasers can be used and that thermal energy generated from a resistive coil or Curie point element may be used as well." Thus it is undeniable that Goldman et al.'s ('084) "passing reference to the use of lasers" is an explicit direction to one of ordinary skill in the art to employ a laser as that which generates the heating energy. In view of this, and in view of the fact that Goldman is totally silent with regard to the type of laser to be used and the wavelength of laser energy to be used (see applicant's arguments submitted June 27, 2005, page 15, third sentence of the second full paragraph), one of ordinary skill in the art would of necessity look to the art of tissue heating to determine the appropriate wavelengths, and/or lasers to use.

Applicant then launches into a discussion of the Navarro reference, despite the fact that this reference has been nowhere applied to to any of the claims at bar. Applicant also notes Dew et al.'s teaching that the dominant wavelength of the Nd:YAG space is 1.06 μ . Next applicant asserts that such a wavelength is used by Makower et al, despite the fact that Makower et al discloses no wavelength in particular.

In view of these facts, applicant's assessment that "the Goldman reference is profoundly flawed as a reference with regard to the claims." is clearly erroneous.

Next, applicant argues that the Dew et al. reference is drawn to a non-destructive method and notes that do seeks to substantially reproduce the prior tissue structure. The examiner must respectfully note, however, that Dew et al. are aware of the use of lasers to both burn tissue (see for example column 1, lines 43 to 61) and denature tissue (column 4, lines 3 to 17). It is interesting to note that Dew et al. specifically discuss, at column 4, lines 7, the use of the method for wound closure, which necessarily requires the destruction of blood vessels to prevent the continuing flow of blood from the wound. Dew et al. extensively discuss that it is, in addition to the wavelength, the precise control of the laser parameters such as spot size and exposure time that yields the desired results. Thus clearly, one having ordinary skill in the art would understand that the wavelength of Dew et al. could be used to destroy tissue as well given the use of the appropriate parameters, and thus is completely suitable for use as the laser wavelength in the laser embodiment of the method of Goldman et al. ('084).

Regarding the combination including Roth, applicant merely argues that Roth does not teach the treatment of varicose veins and thus does not cure the deficiencies of the combination of Goldman et al. ('084) and Dew et al. However, as the combination of Goldman et al. ('084)

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and Dew et al. is not deficient. Roth does not need to discuss the treatment of varicose veins. Similarly, with regard to the rejection, including Conn applicant again argues that the treatment of varicose veins is not taught, however, it is not necessary for Conn to do so for the rejection to be proper.

With regard to the combination of Makower et al., applicant argues that the absence of any teaching with regard to the claimed laser wavelength makes Makower et al. "fundamentally deficient as a reference." The examiner cannot agree. As with Dew et al., Makower et al. is concerned with heating tissue and also carefully controls the heating. Further Makower et al. are also concerned with precisely controlling the amount of heat that is deposited in tissue. Therefore, the combination is proper and reads on the claims.

Applicant also provides evidence of nonobviousness in the form of information of commercially available devices used to treat varicose veins. In short, applicant asserts that as several competitors have produced products employing laser wavelengths in the 500 to 1100 nm range of the use of laser wavelengths outside of this range for this purpose, cannot be obvious. The examiner must respectfully disagree. The teachings of Goldman et al. ('084) that it is important to heat tissue and that the type of energy used to heat the tissue can be of a variety of forms, so long as the tissue temperature is raised to the appropriate level and of Dew et al. ~~left that~~ ^{now} 1.32 μ radiation can be used to effectively heat tissue clearly suggest to one of ordinary skill in the art that this wavelength can be used efficaciously in the treatment of varicose veins. The mere fact that others have chosen other wavelengths to perform the heating that destroys varicose veins is insufficient to overcome the weight of the examiner's *prima facie* case of obviousness.

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Claims 1, 2, 6, 7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al. Goldman et al ('084) teach a method as claimed, but do not specify a wavelength. Dew et al teach the desirability of using 1.3 micron radiation to treat tissue. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the method of Goldman et al ('084), since Goldman et al ('084) teach no particular wavelength, and since the wavelength of Dew can destroy (denature) the proteins, but allow near normal tissue to take it's place, thus producing a method such as claimed.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Roth et al. Roth et al teach employing pull back rate as claimed, noting that the desired rate is dependent on the laser energy. It would have been obvious to the artisan of ordinary skill to employ a pull back as claimed, since these are known in the art and provide no unexpected result and to initiate pulling prior to energy application, since the problem of tissue adhesion is notorious in the art official notice of which is hereby taken, thus producing a method such as claimed.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Conn et al. Conn et al teach a diffusing tip as claimed, it would have been obvious to the artisan of ordinary skill to employ a tip as taught by Conn et al, since this would provide a uniform distribution of light and would prevent over or under treatment of tissue different areas of tissue, while thus producing a method such as claimed.

Claim 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al as applied to claims 1, 2, 6, 7 and 25 above, and further in view of Makower et al. Makower et al teach controlling the heating of tissue using infrared sensing. It would have been obvious to the artisan of ordinary skill to employ the temperature sensor of Makower et al in the method of Goldman et al ('084) since these are equivalents, as taught by Makower et al, thus producing a method such as claimed.

Claim 14-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Roth et al and Dew et al. Makower et al teach a device as claimed except the particular laser wavelength and the pull back mechanism. Dew et al teach a wavelength as claimed for treating tissue. Roth et al teach a pull back mechanism providing the claimed rate. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the device of Makower et al, since Makower et al teach the use of an Nd:YAG laser, which necessarily produces this radiation, as taught by Dew et al and to employ the pull back mechanism of Roth et al, since this enables uniform treatment along the surface, as taught by Roth et al, thus producing a device such as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Dew et al and Roth as applied to claims 14-17 and 20-23 above, and further in view of Conn et al. Conn et al teach a diffusing tip on an introducer for a fiber. It would have been obvious to the artisan of ordinary skill to include the diffuser of Conn et al in the device of Makower et al, since this reduces problems due to breakage, as taught by Conn et al, thus producing a device such as claimed.

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Applicant's arguments filed June 27, 2005 have been fully considered but they are not persuasive, for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak, can be reached on Monday, Tuesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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